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December 16, 1999

Dockets Management Branch (HFA-305)
Food and **Drug** Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

DOCKET # 97N-484S

To Whom It May Concern,

I am writing to express concern about an aspect of the Food and Drug Administration's proposed regulation Relating to the Suitability Determination for Donors of Human Cellular and Tissue-Based Products (21 C.F.R. § 127.1).

The proposed regulation would require that a donor of cells or tissue (including semen) "who is identified as having risk factors for . . . any of the relevant communicable disease agents for which screening is required . . . shall be determined to be unsuitable." 21 C.F.R. § 127.1.75. The regulation itself does not state what those risk factors entail; the supplementary information that accompanies the proposed regulation, **however**, states that the screening of the donor "should include questions about **whether or** not the donor met certain descriptions or engaged in activities or behaviors considered' to place the donor at increased risk for a relevant communicable disease." Federal Register, Vol. 64, No. 189 at 52703.

My concern with this language is that gay men as a class may be prohibited from donating semen because of the perceived risk of HIV transmission (in the same way, for example, that gay men are not allowed to donate blood). If that is the way in which the regulation is interpreted, it raises serious constitutional issues for those gay men who are interested in donating semen in order to procreate. The right to procreate is a fundamental right under the United States Constitution. See Skinner v. Oklahoma, 316 U.S. 535 (1942), that interferes with that right must be narrowly tailored to advance a compelling state interest. Clearly, the prevention of HIV transmission constitutes a compelling state interest but a complete ban on the ability of gay men to donate semen (when those men donate the semen in order to reproduce) would not be a narrowly tailored way of advancing the state interest.

It is important to keep in mind that the proposed regulations already call for the testing of potential donors for HIV. See 29 C.F.R. § 1271.80(a) and 29 C.F.R. § 1271.85 (a)(1)(2). Furthermore, the regulations call for the quarantining of specimens pending the determination of donor suitability. See 29 C.F.R. § 1271.60. While I do not have the expertise to comment on the need for these two precautions, if the FDA were to conclude that the two precautions are necessary, they would seem to be sufficient to achieve the agency's goal of addressing the risk of HIV transmission.

97N-484S

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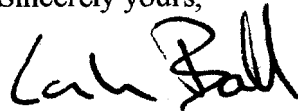
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For these reasons, I would strongly urge the FDA not to issue regulations (or interpretative guidances) that could be interpreted as a categorical rule that would prohibit gay men from donating semen. In my estimation, such an action by the FDA would be unconstitutional.

Please do not hesitate to contact me if I can be of assistance on this issue.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Carlos A. Ball". The signature is fluid and cursive, with the first name "Carlos" written in a larger, more prominent script than the last name "Ball".

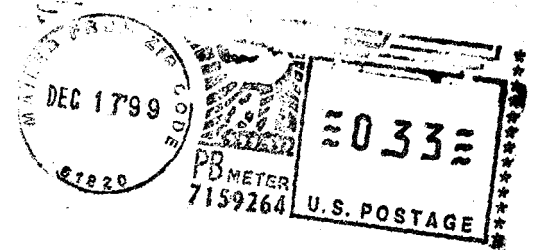
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